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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,265	10/27/2003	Rima Kaddurah-Daouk	MBZ-001CP	4692

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LAHIVE & COCKFIELD
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BOSTON, MA 02109

EXAMINER	
CALAMITA, HEATHER	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/695,265	KADDURAH-DAOUK ET AL.	
	Examiner	Art Unit	
	Heather G. Calamita, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *91-139* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *91-139* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 91-93 and 95-97, drawn to a method for metabolomically facilitating the diagnosis of a nervous system disorder, classified in class 514, subclass 2.

II. Claims 94-97 and 125-139, drawn to a method for metabolomically monitoring the effectiveness of a therapeutic agent in clinical trials, classified in class 424, subclass 2.

III. Claims 98-109, drawn to a method for generating a small molecule profile of a cellular compartment, classified in class 359, subclass 900.

IV. Claim 110, drawn to disease relevant small molecules, classified in class 514, subclass 2.

V. Claims 111-115, drawn to a method for identifying small molecules regulated modulated or associated with a gene, classified in class 435, subclass 287.2.

VI. Claims 116-118, drawn to a method for identifying potential cell drug targets, classified in class 424, subclass 2.

VII. Claim 119, drawn to cellular components, classified in class 359, subclass 900.

VIII. Claims 120-122, drawn to a library of small molecules of a cellular compartment of a cell, classified in class 359, subclass 900.

IX. Claim 123, drawn to a method for determining whether small molecule profiles are from the same individual, classified in class 435, subclass 287.1.

X. Claim 124, drawn to a pharmaceutical composition, classified in class, subclass.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II, III, V, VI, IX are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or

can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the instant specification does not disclose that these methods would be used together and they have different modes of operation. The first method for metabolomically facilitating the diagnosis of a nervous system disorder (group I) and the second method for metabolomically monitoring the effectiveness of a therapeutic agent in clinical trials (group II), and the third method for generating a small molecule profile of a cellular compartment (group III), and the fourth method for identifying small molecules regulated modulated or associated with a gene (group V) and the fifth method for identifying potential cell drug targets (group VI) and the sixth method for determining whether small molecule profiles are from the same individual (group IX) and the seventh method for identifying small molecules relevant to a nervous system disorder (group XI) comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. The first method, a method for metabolomically facilitating the diagnosis of a nervous system disorder utilizes a utilizes a small molecule profile to determine a predisposition for developing a nervous system disorder and involves diagnosis of the disorder. The second method, a method for metabolomically monitoring the effectiveness of a therapeutic agent in clinical trials utilizes a small molecule profile to predict a subject's response to a therapeutic agent. The third method, a method for generating a small molecule profile of a cellular compartment analyzes a small molecule profile to determine the identity of the small moleuces in the cellular compartment. The fourth method, a method for identifying small molecules regulated modulated or associated with a gene utilizes a small molecule profile of a cellular compartment from a genetically modified source. The fifth method, a method for identifying potential cell drug targets involves labeled disease relevant small molecules and identifying interactions between cell compartments and the labeled small molecules. The sixth method, a method for determining whether small molecule profiles are from the same individual involves one or more samples from an individual and comparing small molecule

profiles and determining whether the small molecule profiles are from the same individual. The seventh method, a method for identifying small molecules relevant to a nervous system disorder utilizes at least a small molecule profile of someone with a nervous system disorder and identifies molecules relevant to the disorder but does not involve diagnosis of the disorder. These methods are divergent in materials and steps and for these reasons the Inventions I, II, II, V, VI, IX and XI are patentably distinct. Furthermore, the distinct steps and products require separate and distinct searches. As such, it would be burdensome to search the inventions of Groups I, II, II, V, VI, IX and XI together.

Inventions IV, VIII, X and I, II, III, V, VI, IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the disease relevant molecules can be used in a variety of assays such as PCR.

Inventions VII and I, II, III, V, VI, IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case cellular components can be used in a variety of assays such as ELISA, PCR, Electrophoresis.

Because these inventions are distinct for the reasons given above and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

2. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in

accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Correspondence

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

hgc

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
5/15/06